SCHEDULING STATUS:
S3

PROPRIETARY NAME AND DOSAGE FORM:
BECOPLEX IDO (Injection)

COMPOSITION:
Injection of vitamin B complex, each ml contains:

Thiamine Hydrochloride	10 mg
Riboflavin	2 mg
Pyridoxine Hydrochloride	5 mg
Nicotinamide	100 mg
Calcium Pantothenate	5 mg

Excipients:
Disodium edetate and polyoxyl 35 castor oil (cremophor EL).
Preservative: Benzyl Alcohol 2 % v/v

PHARMACOLOGICAL CLASSIFICATION:
A22.1 Multivitamins and multivitamins with minerals

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
The pharmacological action of the single vitamins is generally known and described in the literature.
Vitamin B12 is present in the body mainly as methyl cobalamin and as adenosyl cobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methyl malonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.
Thiamine combines adenosine triphosphate (ATP) to form a co-enzyme, thiamine pyrophosphate (thiamine diphosphate, carboxylase), which is necessary for carbohydrate metabolism.
Pyridoxine is converted in erythrocytes to pyridoxal phosphate and pyridoxamine phosphate which act as co- enzymes for various metabolic functions affecting protein, carbohydrate and lipid utilisation.
Nicotinamide is a water-soluble vitamin B substance that is converted to nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate (NADP). These co-enzymes are involved in electron transfer reactions in the respiratory chain.
Calcium Pantothenate (Pantothenic acid) is traditionally considered to be a vitamin B substance. It is a component of co-enzyme A which is essential in the metabolism of carbohydrate, fat and protein.
The clinical effect of a combination product like BECOPLEX IDO is generally known through many years of use.

INDICATIONS:
Vitamin B deficiency:
- Beri-Beri, Pellagra
- Stomatitis, Glossitis
- Gastrointestinal lesions with decreased absorption (e.g. enteritis, ulcerative colitis and steatorrhea)
- Anorexia
- Hyperemesis due to X-ray intoxication
- Conditions associated with an increased Vitamin B requirement (e.g. pregnancy, lactation, hyperthyreosis and diabetes)
- Neuritis, neuralgia
- Polyneuritis (e.g. alcoholic)
- Adjuvant in the treatment with antibiotics and chemotherapeutics.

CONTRAINDICATIONS:
Known hypersensitivity to any of the ingredients, including excipients (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS:
BECOPLEX IDO is intended for intramuscular injection, and should not be administered by any other route. Symptoms of peripheral sensory neuropathy (paraesthesia) may occur. If such symptoms do occur, the dosage of BECOPLEX IDO should be reviewed and treatment discontinued, if necessary.
Neuropathies have been observed under long-term administration, 6 to 12 months, of daily dosages exceeding 50 mg pyridoxine hydrochloride (vitamin B6) as well as in short-term administration (over 2 months) of more than 1 g vitamin B6 per day.
The recommended dosage should therefore not be exceeded (see DOSAGE AND DIRECTION FOR USE). Potentially serious allergic reactions may occur, during or shortly after, parenteral administration of BECOPLEX IDO.
There has been a report of life-threatening eosinophilic pleuropericarditis associated with the use of calcium pantothenate, as in BECOPLEX IDO. Treatment must be discontinued should this occur.
Effects on ability to drive and use machines:
Patients should not drive or operate any machinery before they know how they are affected by BECOPLEX IDO.
INTERACTIONS:
Thiamine hydrochloride:
Thiamine is inactivated by 5-flourouracil as the latter competitively inhibits the phosphorylation of thiamine to thiamine pyrophosphate.
Loop diuretics, such as furosemide, that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy; thus, lowering the thiamine level.
Beverages containing sulphites (e.g. red wine) enhance thiamine degradation.
Pyridoxine hydrochloride:
Pyridoxine reduces the effects of levodopa, but this does not occur if a dopa decarboxylase inhibitor is also given.
Pyridoxine reduces the activity of altretamine.
Pyridoxine has also been reported to decrease serum concentrations of phenobarbitone and phenytoin. Concurrent administration of pyridoxine antagonists (such as isoniazid (INH), hydralazine, D-penicillamine, cycloserine and oral contraceptives) may increase the pyridoxine requirement.

HUMAN REPRODUCTION:
The safety of BECOPLEX IDO in pregnancy and lactation has not been established.
BECOPLEX IDO should not be used in pregnancy and lactation.
Vitamin B6 is associated with damage to spermatogenesis in rats.

DOSAGE AND DIRECTIONS FOR USE:
2 ml 2-6 times weekly for 1-2 weeks. The injections should be given intramuscularly. Parenteral treatment is especially indicated for alcoholics and other patients in whom malabsorption from the intestinal tract can be expected.

SIDE EFFECTS:
Immune system disorders
Less frequent: Hypersensitivity reactions such as sweating, tachycardia and skin reactions like itching, rash and urticaria as well as anaphylaxis.
Nervous system disorders
Frequency unknown: Peripheral sensory neuropathy (see WARNINGS AND SPECIAL PRECAUTIONS).
Skin and subcutaneous tissue disorders
Less frequent: Eczematous skin alterations and a benign form of acne.
Gastrointestinal disorders
Frequency unknown: Nausea, vomiting, diarrhoea and abdominal pain.
Renal and urinary disorders
Frequency unknown: Bright yellow discolouration of urine.
General disorders and administrative site conditions
Frequency unknown: Injection site reactions, including pain and swelling.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In the event of an overdose, side effects may be exacerbated and exaggerated.
Treatment is symptomatic and supportive.

IDENTIFICATION:
A clear yellow liquid free from particles.

PRESENTATION:
10 ml rubber-capped vials.

STORAGE INSTRUCTIONS:
To be stored between 2-8 °C. Protect from light.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:
H2611 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
BIOTECH LABORATORIES (PTY) LTD
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
Date of registration: 06 May 1976
Date of revised professional information: 19 January 2018

SKEDULERINGSTATUS:
S3

HANDELSNAAM EN DOSSERINGS VORM:
BECOPLEX IDO (Inspuiting)

SAMESTELLING:
Inspuiting van Vitamine B complex, elke ml bevat:

Tiamien Hidrochloried	10 mg
Riboflavien	2 mg
Piridoksien Hidrochloried	5 mg
Nikotinamied	100 mg
Kalsium Pantotenaat	5 mg

Onaktiewe hulpstowwe:
Natrium karbonaat edetaat en polyoxyl 35 kasterolie (cremophor EL).
Preserveringsmiddel: Benzyl Alkohol 2 % v/v

PHARMAKOLOGIESE KLASSIFIKASIE:
A22.1 Multivitamiene and multivitamiene met minerale

PHARMAKOLOGIESE WERKING:
Pharmakodinamiese eienskappe
Die farmakologiese werking van die enkele vitamiene is algemeen bekend en beskryf in die literatuur.
(Vitamien B12 is teenwoordig in die liggaam hoofsaaklik as metiel kobalamien en as adenosiel kolabamien en hidroksiekobalamien. Dit werk as koënsieme in the trans-metielasie van homosistien na metionien; in die isomerisasie van metielmaloniel koënsiem na suksiniel koënsiem en met folate in verskeie metaboliese weë onderskeidelik. Tekort aan Vitamien B12 meng in met hemopoiëse en lei tot megoblastiese anemie.
Tiamien kombineer adenosine trifosfaat (ATP) om 'n koënsiem, tiamien pirofosfaat (tiamien difosfaat, karboksilase) te vorm, wat noodsaaklik is vir koolhidraat metabolisme.
Piridoksien word omgeskakel in eritrosiete tot piridoksale fosfate en piridoksamien fosfate wat werk as koënsieme vir verskeie metabolise funksies wat proteïen, koolhidrate en lipiede benodig.
Nikotinamiede is water oplosbare vitamiene B stowwe wat omskakel word tot nikotinamied adenine dinukleotied en nikotinamied adenine dinukleotied fosfaat (DADF), Hierdie koënsieme is betrokke in elektron oordrag reaksies in die respiratoriese ketting.
Kalsium Pantotenaat (Patotenaat suur) is tradisioneel gesien as a vitamien B stof. Dit is a komponent of koënsiem A wat noodsaaklik is in die metabolisme van koolhidrate, vette en proteïene.
Die kliniese effek van 'n kombinasie produk soos BECOPLEX IDO is algemeen bekend as gevolg van menige jare se gebruik.

INDIKASIES:
Vitamien B tekort:
• Beri-Beri, Pellagra
• Stomatitis, Glossitis
• Gastrointestinale letsels met ingeperkte absorpsie (bv. Enteritis, ulseratiewe kolitis en steatorrhea)
• Anoreksie
• Hiperemese as gevolg van X-straal vergiftiging
• Kondisies geassosieer met verhoogde Vitamien B behoeftes (bv. Swangerskap, laktasie, hipertireose en diabetes)
• Neuritis, neuralgie
• Polineuritis (bv. Alkohol afhanklikheid)
• Aanvullend tydens behandling met antibiotika en chemoterapie.

KONTRA-INDIKASIES:
Bekende hipersensitiwiteit tot enige van die bestandele, insluitende die onaktiewe hulpstowwe (sien SAMESTELLING)

WAARKSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
BECOPLEX IDO is aangedui vir intramuskulêre inspuiting, en mag nie deur enige ander roete toegedien word nie.
Simptome van perifere sensoriese neuropatie (parastesie) mag voorkom. Indien hierdie simptome voorkom, moet die dosering van BECOPLEX IDO hersien word, of behandeling gestaak word, indien nodig.
Neuropatïe is al aangemeld gedurende langtermyn toediening, 6 tot 12 maande, van daaglikse doserings wat 50 mg piridoksien hidrokloried (vitamien B6) bevat, sowel as korttermyn toediening (van meer as 2 maande) of meer as 1 g vitamien B6 per dag.
Die aanbevole dosis moet daarom nie oorskry word nie (sien DOSERING EN GEBRUIKSAANWYSINGS)
Potensiële ernstige allergiese reaksies mag voorkom, gedurende of kort na parenterale toediening van BECOPLEX IDO.
Lewens-bedreigende eosinofiliese pleuroperikarditis geassosieer met die gebruik van kalsium pantopentaat, soos in BECOPLEX IDO, is eenmalig vantevore aangemeld. Behandling moet onmiddelik gestaak word indien dit voorkom.
Effek op vermoë om te bestuur of gebruik van masjinerie:
Pasiente moet dit vermy om te bestuur of masjinerie te gebruik, voordat hul weet hoe BECOPLEX IDO hul beïnvloed.

INTERAKSIES:
Tiamien Hidrochloried:
Tiamien word gedeaktiveer deur 5-flourasiel as the laasgenoemde die fosforilasie van tiamien tot tiamien fosfaat kompeterend inhibeer.
Lus diuretika, soos furosemide, wat absorpsie in die buise inhibeer, mag verhoogde uitskeiding van tiamien tydens langtermyn terapie veroorsaak, wat dus die tiamien vlakke sal verlaag.
Drankies wat sulfiete bevat (bv. rooi wyn) versnel die degredasie van tiamien.
Piridoksien Hidrochloried:
Piridoksien verhoog die effek van levodopa, maar dit kom nie voor wanneer 'n dopa-karboksilase inhibeerder ook toegedien word nie.
Piridoksien verminder die aktiwiteit van altretamien.
Dit is al aangemeld dat piridoksien die serum konsentrasie van fenobarbiton en phenotoïen kan verlaag.
Gesamentlike toediening van piridoksien antagoniste (soos isoniazid (INH), hydralazine, D-penisilamien, sikloserien en orale kontrasepsie middels) mag die vereiste aan piridoksien verhoog.

MENSLIKE REPRODUKSIE:
Die veiligheid van BECOPLEX IDO tydens swangerskap en laktasie is nie vasgestel nie.
BECOPLEX IDO mag nie tydens swangerskap en laktasie gebruik word nie.
Vitamien B6 is al geassosïeer met belemmering van spermatogenese in rotte.

DOSIS EN GEBRUIKSAANWYSINGS:
2 ml 2-6 keer per week vir 1-2 weke. Die inspuiting moet intramuskulêr toegedien word. Parenterale behandeling work aangedui in veral die behandeling van alkoholiese pasiente waar wanabsorpsie van die intestinale kanaal vermoed word.

NEWE EFFEKTE:
Immuunstelsel-afwykings
Minder algemeen: Hipersensitiwiteits reaksies soos oormatige sweet, tagikardie en vel reaksies soos jeuk, uitslag en utikaria asook anafilakse.
Senuwee sisteem afwykings
Voorkoms onbekend: Perifere sensoriese neuropatie (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS).
Vel en subkutane weegsel afwykings
Minder algemeen: Eksematiese vel veranderinge en 'n benigne vorm van aknee.
Gastrointestinale afwykings
Voorkoms onbekend: Naarheid, braking, diarrhoea en abdominale pyn.
Renal and urinary disorders
Voorkoms onbekend: Helder geelkleurige urine.
Algemene afwykings en toedienings area kondisies
Voorkoms onbekend: Inspuiting area reaksies, insluitend pyn en swelling.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
In geval van oordosering, kan die newe-effekte vererger en meer voorkom.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Helder geel vloeistof vry van enige partikels.

AANBIEDING:
10 ml rubber-bedekte flesse.

BEWARINGSINSTRUKSIES:
Bewaar tussen 2-8 °C. Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER:
H2611 (Act 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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Grond Vloer, Block K Wes, Central Park
400 16de Road, Randjespark, Midrand, 1685
Suid Afrika

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